DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2015

NuVasive, Incorporated
Mr. Jeremy Markovich
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K141665
Trade/Device Name: NuVasive® CoRoent® System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 12, 2015
Received: February 13, 2015

Dear Mr. Markovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141665

Device Name
NuVasive® CoRoent® System

Indications for Use *(Describe)*

The NuVasive CoRoent Lumbar System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. The devices are to be used in patients who have had at least six months of non-operative treatment.

The CoRoent Lumbar System (L and XL platforms) is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Jeremy Markovich
Associate Manager, Regulatory Affairs
NuVasive, Inc.
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: February 12, 2015

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® System*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Lumbar
Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	MAX

C. Predicate Devices

The subject *CoRoent System* is substantially equivalent to the primary predicate device, *NuVasive CoRoent System* (K071795), and the following additional predicate devices: *Depuy Cougar Implant System* (K113348), *NuVasive CoRoent Titanium System* (K120918), *NuVasive Brigade Hyperlordotic System* (K123045), *NuVasive Expandable Lumbar Interbody System* (K130820), *InterForm Interbody Cage System* (K131082), *NuVasive CoRoent XL Sterile Implants* (K132601), *Alphatec Novel Spinal Spacer System* (K080699), *NuVasive CoRoent Ti-C System* (K140319), *Pioneer Surgical Technology, Inc. Interbody Fusion (IBF)/Vertebral Body Replacement (VBR) System* (K133455), *Stryker Spine AVS PL PEEK Spacers* (K090816), and *Globus Medical Inc. Caliber Spacers* (K123231).

D. Device Description

The NuVasive® CoRoent System is manufactured from PEEK-OPTIMA® Optima LT1 (Polyether-ether-ketone) conforming to ASTM standard F2026, Ti-6Al-4V ELI conforming to ASTM standard F136/1472 or Tantalum conforming to ASTM standard F560 or ISO 13782. These implants are available in a variety of shapes and configurations for PLIF/TLIF, XLIF and ALIF approaches, with heights ranging from 6 – 24 mm, widths ranging from 9 – 42 mm, lengths ranging from 20-65 mm and lordotic angles ranging from 0° - 20°, to suit the individual pathology and anatomical conditions of the patient. The hollow aperture allows for packing of autogenous bone graft. Teeth on the superior and inferior surface of the implants provide resistance to expulsion.

Both the subject device and its accessory surgical instruments are packaged as non-sterile, to be sterilized by the end user. In addition, the implants are also offered in sterile packaged versions.

E. Intended Use

The NuVasive CoRoent Lumbar System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. The devices are to be used in patients who have had at least six months of non-operative treatment. The CoRoent Lumbar System (L and XL platforms) is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *CoRoent System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic axial compression and compression shear per ASTM F2077
- Finite Element Analysis
- Subsidence testing and analysis per ASTM F2267

The results demonstrate that the subject *CoRoent System* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *CoRoent System* has been shown to be substantially equivalent to legally marketed predicate devices.